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10/635,091

08/06/2003

Anne M. Pianca

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EXAMINER

KAHELIN, MICHAEL WILLIAM

ART UNIT

PAPER NUMBER

3762

MAIL DATE

DELIVERY MODE

04/06/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/635,091

Applicant(s)

PIANCA ET AL.

Examiner

MICHAEL KAHELIN

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period **will** apply and **will** expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply **will**, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 14-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/25/2009 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner was unable to find support for the newly-amended limitation "being constructed to be physically continuous throughout the layer" in either paragraphs 0050 and 0051, or Figures 4 and 5. There is no discussion of the "continuity" of the outer covering in paragraphs 0050 and 0051. Further, Figures 4 and 5 do not even show the entirety of the stylet, and thus cannot provide a basis for a layer that is continuous "throughout." Further, as textual support is

lacking, there is no reason to believe that the diagonal lines in the sheath in Figures 4 and 5 do not show a "wrapped" sheath, similar to Soukup's (US 6,755,794) Figure 3.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 5-11, and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Soukup (US 6,755,794, hereinafter "Soukup").

6. In regards to claim 1, Soukup discloses a metal outer covering material being constructed to be physically continuous throughout the layer (Fig. 1, element 14; a single, physically continuous "ribbon" is wrapped around the inner core, i.e., continuous from one end of the spiral to the other end); a solid inner core made of inner core material and having a solid lateral cross-section (element 12; col. 5, lines 15-21); and wherein the outer and inner materials have different elastic and buckling properties (col. 5, lines 14-16 and 23-24).

7. In regards to claim 5, the stylet is isodiametric (Figs. 2 and 3).

8. In regards to claims 6 and 8, the outer covering has a variable wall thickness/circumference in the "loosened state" Figure 1.

9. In regards to claims 7 and 9, the outer covering has a substantially constant wall thickness in the “tightened state” of Figures 2 and 3, and the wall itself (ribbon 14) has a “substantially constant wall thickness in either state (Figs. 1-3).
10. In regards to claim 10, the core has a substantially constant thickness along the length of the stylet (Fig. 1).
11. In regards to claim 11, the core is Nitinol and the covering material is stainless steel (col. 5, lines 14-16 and 23-24).
12. In regards to claim 13, the inner core has been “pre-stressed” to operate on the compression side of the stress-strain curve (col. 2, lines 52-61).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 2-4 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soukup. Soukup discloses the essential features of the claimed invention except for the claimed stainless steel alloys, or that the outer covering is a super-elastic material and the inner core is a linear elastic material. It is well known to provide stylets with the claimed stainless steel alloys to provide the predictable results of using a readily available and biocompatible material, and to provide outer coverings of a super-elastic material and inner cores of linear elastic material to provide the predictable result of a stylet with the desired combination of mechanical properties. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Soukup's invention by providing the claimed stainless steel alloys to provide the predictable results of using a readily available and biocompatible material, and to provide an outer covering of a super-elastic material and inner core of linear elastic material to provide the predictable result of a stylet with the desired combination of mechanical properties.

Response to Arguments

16. Applicant's arguments filed 2/25/2009 have been fully considered but they are not persuasive. In regards to the restriction requirement of 9/10/2008 and made final in the communication of 12/30/2008, Applicant argued that the two restricted groups are not mutually exclusive because the two groups may be overlapping in scope. Applicant reasoned that the plain meaning of "mutually exclusive" indicates a relationship wherein elements of invention II must be preclude from invention I and vice-versa. Applicant then concluded that, since these are "comprising" claims, invention I could include the

elements of invention II (or any other elements) and vice versa, and thus the inventions are not mutually exclusive. However, taken to its logical extreme, this reasoning would merely require a single shared limitation to defeat a ground for restriction. For instance, Applicant could submit claims drawn to a starter for a car and an implantable electrical lead in the same application because they both comprise a wire. This is addressed in MPEP 806.05, where “mutually exclusive” is not defined under its plain meaning, but as “if a first invention would not infringe a second invention, and the second invention would not infringe the first invention.” This is clearly the case with the restricted groups, as neither invention includes all the elements of the other invention.

17. Applicant further argued that Soukup fails to disclose a “physically continuous” outer covering because of the open windings. However, the Examiner is of the position that the limitation “physically continuous” does not preclude open windings. As Soukup's layer is a single piece of flat wire spring, it is “physically continuous” from one end of the wire spring to the other end of the wire spring. Further, the layer is “physically continuous throughout” in the radial direction (i.e., from the outer surface toward the center of the stylet).

18. Applicant further argued that claims 6 and 8's recitation of variable wall thickness and variable outer circumference is not disclosed by Soukup because the wall thickness of the compression member will not change depending on whether the member is tightened or loosened. However, referring to, e.g., Figure 1 of Soukup's disclosure, the Examiner is considering the wall thickness to be analyzed by envisioning the cross-section of the stylet in the plane perpendicular to the longitudinal axis of the stylet. As

this plane traverses the longitudinal axis, the outer covering has a variable thickness/outer circumference of either the thickness of the wire spring in some areas or zero in the open windings. This is in contrast to, e.g., claims 5 and 7 where the stylet is considered in its state shown in Figures 2 or 3, or from the perspective of a helical plane that follows the winding of the wire spring.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL KAHRELIN whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 10/635,091
Art Unit: 3762

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/Michael Kahelin/
Examiner, Art Unit 3762

/Angela D Sykes/
Supervisory Patent Examiner, Art Unit 3762